1092691

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is:	OCT	1	5	20	00	19
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1. Submitter:

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Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8611 9549 Fax: +86 755 2658 2680

Contact Person:

Sheng Haobin
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: July 31, 2009

2. Device Name: DC-7 Diagnostic Ultrasound System

Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Marketed Device:

DC-7 Diagnostic Ultrasound System is substantially equivalent to the following devices: Mindray DC-3 (K#091491), Mindray DC-6 (K#072164), GE Vivid S6 (K#071985), Siemens X300 (K#090276), GE Logiq P5 (K#060993), GE Vivid 7 (K#060542).

4. Device Description:

The DC-7 Diagnostic Ultrasound System is a general purpose, portable, software controlled, ultrasound diagnostic system. This system is a Track 3 device that employs an array of probes that include linear array probe, convex array probe, phased array probe and volume probe with a frequency range of approximately 2.0 MHz to 12.0 MHz.

5. Intended Use:

The DC-7 diagnostic ultrasound system is designed for M, B, pulsed doppler, continuous Doppler, color Doppler, power Doppler modes, and combined modes (i.e. B/M Mode). The system is indicated for fetal, abdominal, pediatric, small organ (breast, thyroid, and testes), cephalic (neonatal and adult), transrectal, transvaginal, peripheral vascular, musculo-skeletal (conventional and superficial), and cardiac (neonatal and adult). The system includes optional biopsy needle guides that attach to the transducers.

6. Safety Considerations:

The DC-7 Diagnostic Ultrasound System had been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD 3: 2004 Standards for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, IEC 60601-1-4 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the DC-7 Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.





Food and Drug Administration 10903 New Hampshire Avenue Document Control Room W-066-0609 Silver Spring, MD 20993-0002

JAN - 4 2010

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. % Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K092691

Trade/Device Name: DC-7 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed Doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: September 29, 2009 Received: September 30, 2009

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of October 15, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-7 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5A, C5-2 V10-4, V10-4B 6C2 7L4A, 7L5, L12-4, L7-3, L11-4 If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Mr. Paul Hardy at (301) 796-6542.

Sincerely yours,

Janine M. Morris

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

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Center for Devices and Radiological Health

Enclosure(s)

System	<u>×</u>		Transduce	er
Model:		DC-7		_
510(k) Number(s)				
_				
<u> </u>				Mode of Operation

		Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)				
Ophthalmic							:					
Fetal	N	N	N		N	N	N	Note1,2, 3, 4,7,8				
Abdominal	N	N	N	N	N	N	N	Note1,2, 3, 4,5,7,8				
Intraoperative (specify)*												
Intraoperative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4,5,7,8				
Small organ(specify)**	N	N	N		N	N	N	Note1, 2, 4,7,8				
Neonatal Cephalic	N	N	N	N	N	N	N	Note1, 2, 4,5,7,8				
Adult Cephalic	N	N	N	N	N	N	N	Note1, 2, 4,5,7,8				
Trans-rectal	N	N	N		N	N	N	Note 1,2,4,7,8				
Trans-vaginal	N	N	N		N	N	N	Note 1,2,4,7,8				
Trans-urethral												
Trans-esoph.(non-Card.)												
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2,4,7,8				
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2,4,7,8				
Intravascular		i										
Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,5,7,8				
Cardiac Pediatric	Ñ	N	N	N	N	N	N	Note 1,2,5,7,8				
Intravascular (Cardiac)												
Trans-esoph.(Cardiac)												
Intra-Cardiac												
Peripheral Vascular	N	N	N		N	N	N	Note 1,2,4,7,8				
Other (specify)***		ì				[<u> </u>					

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.
*Intraoperative includes abdominal, thoracic, and vascular etc.
**Small organ-breast, thyroid, testes, etc.
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note 2: Smart3D
Note 3:4D(Real-time 3D)
Note 4: iScape
Note5: TDI
Note6: Contrast Imaging
Note7: Color M
Note8: Biopsy Guidance
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

System

Diagnostic Ultrasound Indications for Use Form

Transducer

Doppler Doppler Doppler Specify	Model:		3C5.	A, C5-2		_					
Clinical Application B M PWD CWD Doppler Color Doppler Combined C	510(k) Number(s)					•					
Clinical Application B M PWD CWD Doppler Color Doppler Combined C											
B M PWD CWD Doppler (specify) Other (specify) Ophthalmic Fetal N N N N N N N N N N N N N N N N N N N	Clinian Annihanian	<u> </u>	_					<u> </u>			
Fetal N N N N N N N N N N N N N N N N N N N	Chnical Application	В	М	PWD	CWD		-		Other (specify)		
Abdominal N N N N N N N N N N N N N N N N N N N	Ophthalmic					<u> </u>	<u> </u>				
Intraoperative (specify)* Intraoperative (Neuro) Laparoscopic Pediatric N N N N N N N N N N N N N N N N N N N	Fetal	N	N	N		N	N	N	Note 1, 2, 4,7,8		
Intraoperative (Neuro) Laparoscopic Pediatric N N N N N N N N N N N N N N N N N N N	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,7,8		
Laparoscopic Pediatric N N N N N N N N N N N N N N N N N N N	Intraoperative (specify)*										
Pediatric N N N N N N N N N N N N N N N N N N N	Intraoperative (Neuro)										
Small organ(specify)** Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-vaginal Trans-esoph.(non-Card.) Musculo-skeletal Conventional Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Laparoscopic										
Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-vaginal Trans-soph.(non-Card.) Musculo-skeletal Conventional Intrans-soph.(non-Card.) Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Intra-cardiac Intravascular (Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,7,8		
Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-soph.(non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Small organ(specify)**										
Trans-rectal Trans-vaginal Trans-urethral Trans-esoph.(non-Card.) Musculo-skeletal Conventional Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Trans-esoph.(Cardiac) Trans-esoph.(Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Neonatal Cephalic										
Trans-vaginal Trans-urethral Trans-esoph.(non-Card.) Musculo-skeletal Conventional N N N N N N N N N N N N N N N N N N N	Adult Cephalic	T				1					
Trans-urethral Trans-esoph.(non-Card.) Musculo-skeletal Conventional N N N N N N N N N N N N N N N N N N N	Trans-rectal	T									
Trans-esoph.(non-Card.) Musculo-skeletal Conventional N N N N N N N N N N N N N N N N N N N	Trans-vaginal										
Musculo-skeletal Conventional N N N N N N N N N N N N N N N N N N N	Trans-urethral			<u> </u>		i					
Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Intravascular (Cardiac) Intravascular (Cardiac) Intravascular (Cardiac) Intra-Cardiac Peripheral Vascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Trans-esoph.(non-Card.)	\top					i				
Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Intravascular (Cardiac) Intra-Cardiac Peripheral Vascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1, 2, 4,7,8		
Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Irans-esoph.(Cardiac) Intra-Cardiac Intra-Cardiac Peripheral Vascular Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Musculo-skeletal Superficial	1									
Cardiac Pediatric Intravascular (Cardiac) Frans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N N	Intravascular	1									
Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N	Cardiac Adult	Ť T					i T				
Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N	Cardiac Pediatric	1			i						
Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N	Intravascular (Cardiac)	\vdash		\vdash		i					
Intra-Cardiac Peripheral Vascular N N N N N N N N N N N N N N N N N N	Trans-esoph.(Cardiac)	\vdash		\vdash							
Peripheral Vascular N N N N N N N N N N N N N N N N N N		T				i	<u> </u>				
N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B. *Intraoperative includes abdominal, thoracic, and vascular etc. **Small organ-breast, thyroid, testes, etc. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Smart3D Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)		N	N	N		N	N	N	Note 1, 2, 4,7,8		
Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B. *Intraoperative includes abdominal, thoracic, and vascular etc. **Small organ-breast, thyroid, testes, etc. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Smart3D Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Other (specify)										
*Intraoperative includes abdominal, thoracic, and vascular etc. **Small organ-breast, thyroid, testes, etc. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Smart3D Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	N=new indication; P=previously of	leared b	y FDA	; E≃add	ed under	Appendix	E				
**Small organ-breast, thyroid, testes, etc. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Smart3D Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Additional comments:Combined	modes: F	3+M, P	W+B, C	olor + B	, Power +	B, PW +Col	or+ B, Power	r + PW +B.		
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Smart3D Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	*Intraoperative include	es abdon	ninal, tl	horacic,	and vasc	ular etc.					
Note 2: Smart3D Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	**Small organ-breast,	thyroid,	testes,	etc.							
Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note 1: Tissue Harmon	nic Imag	ing. Th	e featur	e does no	ot use cont	rast agents.				
Note 4: iScape Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note 2: Smart3D										
Note5: TDI Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note 3:4D(Real-time 3	(D)									
Note6: Contrast Imaging Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note 4: iScape										
Note7: Color M Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note5: TDI										
Note8: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note6: Contrast Imagis	ng									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note7: Color M	•									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	Note8: Biopsy Guidan	ce									
Concurrence of CDRH, Office of Device Evaluation(ODE)	(PLEASE DO NOT WRITE BEL	OW TH	IS LIN	E-CON	TINUE (ON ANOT	HER PAGE	IF NEEDED)		
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

System		_		Transdu	icer	×		
Model:		V10-4	. V10-4	В				
510(k) Number(s)					•			
					Mode	of Operation		
Clinical Application	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note 1, 2, 4,7,8
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)			l					
Laparoscopic						_		
Pediatric	Ī							
Small organ(specify)**	Ī							
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,7,8
Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,7,8
Trans-urethral	П							
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric	\Box							
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)	i							
Intra-Cardiac	i i							
Peripheral Vascular			·					
Other (specify)***	一							
N=new indication; P=previously o	leared t	y FDA	: E=add	ed under	Appendix	Е		
Additional comments:Combined r	_	•					or+ B, Power	+ PW +B.
*Intraoperative include	-							· · · · · ·
**Small organ-breast,								
**Small organ-breast,								
Note 1: Tissue Harmon	ic Imag	ing. Th	e feature	does no	t use cont	rast agents.		
Note 2: Smart3D								=
Note 3:4D(Real-time 3	D)							
Note 4: iScape								
Note5: TDI								
Note6: Contrast Imagin								
Note7: Color M								
Note8: Biopsy Guidano	ž							
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Prescription USE (Per 21 CF								

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number

System				Transdu	icer	×		
Model:		(6C2					
510(k) Number(s)								
	T				Mode o	f Operation	-	
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1, 2, 4,7,8
Intraoperative (specify)*								_
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1, 2, 4,7,8
Small organ(specify)**								
Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4,7,8
Adult Cephalic	N	N	N		N	N	N	Note 1, 2, 4,7,8
Trans-rectal					1			
Trans-vaginal			\Box					
Trans-urethral								
Trans-esoph.(non-Card.)	1							
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1, 2, 4,7,8
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1, 2, 4,7,8
Intravascular						-		
Cardiac Adult					i			
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)				i				
Intra-Cardiac							_	
Peripheral Vascular	N	N	N		N	N	N	Note 1, 2, 4,7,8
Other (specify)			<u> </u>					
N=new indication; P=previously c	lcared b	v FDA	: E=adde	d under	Appendix	E	<u> </u>	
Additional comments:Combined r							r+ B, Power	+ PW +B.
*Intraoperative include						<u> </u>		
**Small organ-breast,							-	
Note 1: Tissue Harmor				does no	t use contr	ast agents.		
Note 2: Smart3D								
Note 3: 4D(Real-time 3	D)		-					
Note 4: iScape								
Note5: TDI			* *		-			
Note6 : Contrast Imagi	ng							
Note7 : Color M								
Note8 : Biopsy Guidan	ce							
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Prescription USE (Per 21 CFR 801.109)

K092691

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices

Radiological Devices 510(k) Number

System	Transducer	×
Model:	7L4A, 7L5, L12-4, L7-3, L11-4	
510(k) Number(s)		

	Mode of Operation												
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)					
Ophthalmic													
Fetal													
Abdominal	N	N	N		N	N	N	Note 1,2, 4,7,8					
Intraoperative (specify)*													
Intraoperative (Neuro)													
Laparoscopic													
Pediatric	N	N	N		N	N	N	Note 1,2, 4,7,8					
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,7,8					
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,7,8					
Adult Cephalic													
Trans-rectal													
Trans-vaginal													
Trans-urethral													
Trans-esoph.(non-Card.)													
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2, 4,7,8					
Musculo-skeletal Superficial	N	N	N		N .	N	N	Note 1,2, 4,7,8					
Intravascular													
Cardiac Adult													
Cardiac Pediatric													
Intravascular (Cardiac)													
Trans-esoph.(Cardiac)													
Intra-Cardiac													
Peripheral Vascular	N	N	N		N	N	N	Note 1,2, 4,7,8					
Other (specify)***													

N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc. **Small organ-breast, thyroid, testes, etc. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Smart3D Note 3:4D(Real-time 3D) Note 4: iScape Note5: TDI Note6: Contrast Imaging

Note7: Color M Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
Radiological Devices
Radiological Devices

System				Transducer		×		
Model:			L14-6		_			
510(k) Number(s)			-					
• • • • • • • • • • • • • • • • • • • •								
				N	lode of Ope	ration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	Z	N	N		N	N	N	Note 1,2, 4,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2, 4,7
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,7
Neonatal Cephalic	N	N	N		N	N ·	N	Note 1,2, 4,7
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N_		N N	N	N	Note 1,2, 4,7
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2, 4,7
Intravascular					<u> </u>			
Cardiac Adult								
Cardiae Pediatrie								
Intravascular (Cardiac)			İ					
Trans-esoph.(Cardiae)						<u> </u>		
Intra-Cardiac								
Peripheral Vascular	N	N	N		N	N	N	Note 1,2, 4,7
Other (specify)***								
N=new indication; P=previously	cleared	by FDA	; E=added	under Appen	dix E			
Additional comments:Combined	modes:	B+M, P	W+B, Col	or + B, Powcı	r + B, PW +	Color+ B, P	ower + PW +	В
•Intraoperative inclu	des abdo	ominal, tl	horacic, an	d vascular etc	;.			
**Small organ-breas	t, thyroid	d, testes,	etc.					
Note 1: Tissue Harm				loes not use co	ontrast ager	its.		
Note 2: Smart3D	*							
Note 3:4D(Real-time	3D)				-			
Note 4: iScape				-				-
Note5: TDI		·						
Note6: Contrast Imag	ging							
Note7: Color M								
Note8: Biopsy Guida	nce							
(DI CACE DO NOT WRITE RE	LOWIT	uic i ixi	E CONTR	THE ON ANY	OTHED DA	GE IE NEEI	nem)	

Prescription USE (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

oysiciii		_		ranscu	icer			
Model:			2P2				•	
510(k) Number(s)					•			
					•			
	T				Mo	de of Opera	tion	
Clinical Application	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	1	T	П				(-,, -,	
Fetal	T					-		
Abdominal	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)	\top							
Laparoscopic	1						-	
Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Small organ(specify)**	\top	\Box						
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Trans-rectal								
Trans-vaginal	\Box							
Trans-urethral	1							
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	\Box							
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Cardiac Pediatric	N	И	N	N	N	N	N	Note 1, 2,5,7,8
Intravascular (Cardiac)								
Trans-esoph.(Cardiae)								
Intra-Cardiac	П							
Peripheral Vascular								
Other (specify)***								
N=new indication; P=previously o	leared	by FD	A; E=	added un	der Appen	ıdix E		
Additional comments: Combined a	nodes:	B+M,	PW+I	B, Color	+ B, Powe	r + B, PW +	Color+ B, Po	wer + PW +B.
*Intraoperative include	es abdo	minal,	thorac	cic, and v	ascular etc	 		
••Small organ-breast,	thyroid	, teste	s, etc.	-				
Note 1: Tissue Harmon	nic Ima	ging.	The fe	ture doc	s not use c	ontrast agen	ts.	
Note 2: Smart3D								
Note 3:4D(Real-time 3	D)							
Note 4: iScape						,		
Note5: TDI						-		
Note6: Contrast Imagis	ng						-	,
Note7: Color M								
Note8: Biopsy Guidane	ce							
(PLEASE DO NOT WRITE BEL	ow TI	IIS LI	NE-C	UNITHC	E ON AN	OTHER PA	GE IF NEED	ED)
Concurrence of CDRH, O	ffice o	f De	vice l	Evaluat	ion(OD	E)		

Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

34-4-1		• .	CD 4			~	•	
Model:		4	CD4		-			
510(k) Number(s)					-			
· · · · · · · · · · · · · · · · · · ·	<u> </u>							
					Mo	ode of Opera	tion	
Clinical Application	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N	Ī	N	N	N	Note1,2, 3, 4,7
Abdominal	N	N	N		N	N	N	Note1,2, 3, 4,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note1,2, 3, 4,7
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral	1						i i	•
Trans-esoph.(non-Card.)	T							
Musculo-skeletal Conventional	T						Ì	
Musculo-skeletal Superficial							Ì	
Intravascular		i T						
Cardiac Adult	·						i	
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***								
N=new indication; P=previously of	leared	by FD	A: E-	added un	der Apper	dix E		
Additional comments:Combined r							Color+ B, Po	wer + PW +B.
*Intraoperative include	s abdo	minal,	thorac	cic, and v	ascular et	Ç.		
**Small organ-breast,					•			
Note 1: Tissue Harmon	nic Ima	ging.	The fe	ature doe	s not use c	ontrast agen	ts.	
Note 2: Smart3D								
Note 3:4D(Real-time 3	D)							·
Note 4: iScape								
Note5: TDI								
Note6: Contrast Imagi	ng							
Note7: Color M		-				•		
Note8: Biopsy Guidan	ce							
(PLEASE DO NOT WRITE BEL		iis Li	NE-C	ONTINU	E ON AN	OTHER PA	GE IF NEED	ED)
Concurrence of CDRH, O	ffice o	of De	vice l	Evalua	tion(OD	E)		
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Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____